

Role of puncture and aspiration in expectant management of simple ovarian cysts: a randomised study

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See editorial
by Salat-Baroux

Abstract

Objectives—To assess the potential of expectant management for simple ovarian cysts diagnosed by transabdominal or transvaginal ultrasonography. To compare the results of needle aspiration with those achieved with simple observation.

Design—Randomised trial.

Setting—Hospital department of obstetrics and gynaecology.

Subjects—278 women with simple cysts randomly allocated to simple observation (143) or ultrasound guided fine needle aspiration (135) between 1990 and 1994.

Main outcome measures—Resolution of cyst or development of malignancy.

Results—After six months 269 were available for follow up. The rate of resolution was 46% (59/128) with aspiration and 44.6% (63/141) with observation. Only the diameter of the cyst ($P<0.0001$) was a significant independent prognostic factor for resolution in a multivariate analysis. Age and treatment had no significant effect. One woman was subsequently found to have borderline malignant changes on histopathological examination. Her cyst was detected by transabdominal ultrasonography.

Conclusions—Expectant management for up to six months does not cause risks for the patients and allows spontaneous resolution in over a third of cases, avoiding the costs and risks of unnecessary surgery. Aspiration does not provide better results than simple observation

Introduction

A large study performed in 1989 by Campbell *et al* on more than 5000 healthy women found that roughly 6% had adnexal masses, 90% of which were cystic tumours.¹ Grimes and Hughes reported that ovarian functional cysts were the fourth most common gynaecological cause of hospital admission in the United States in the late 1980s.² Moreover, simple ovarian cysts are more common in postmenopausal women than was previously thought.³⁻⁵

The clinical importance of cystic masses and their tendency to turn malignant remains an open question. Clinical experience suggests that simple cystic masses do not usually become malignant.⁶ Surgical treatment of simple benign cystic masses may therefore represent an overtreatment. Several authors have observed that the most adnexal cysts removed are benign or functional^{7,8} and that an increasing proportion are found in asymptomatic women. Nevertheless, we are not aware of any study aimed at evaluating prospectively the benefits of expectant management of apparently benign ovarian cysts.

Despite the experience of other specialties,⁹ diagnostic and therapeutic fine needle aspiration of cysts has never been widely accepted in gynaecology because of the fear of spreading malignant cells in case of unrecognised malignancy and because of the low sensitivity of cytology.¹⁰⁻¹⁵ However, in the last decade increased accuracy of ultrasonography has allowed non-malignant benign cysts to be identified reliably.^{3,16} We previously observed that the puncture of sonographically benign

cysts was feasible and led to resolution in 37.6% of cases.¹¹ Since those cysts which disappeared after puncture might have resolved without any treatment, we conducted this study to compare the efficacy of aspiration of cysts with simple observation.

Subjects and methods

We calculated the size of the study population on the basis of our findings of a rate of resolution of 35% after aspiration¹¹ and an assumed resolution rate of at least 20% for no intervention, which was considered a reasonable estimate by all the doctors in the study. To identify a difference of 15% between aspiration and observation corresponding to a relative reduction in the odds of failure of about 50% ($\alpha=0.05$, two tailed; $1-\beta=80\%$) we needed to recruit 312 women.¹⁷ However, because of difficulties in enrolment towards the end of the study we stopped after 278 subjects.

From June 1990 to November 1994 we enrolled consecutive women who had been referred to our ultrasonography department after detection of an adnexal mass at gynaecological examination (150) or sent for second level examination after detection of an adnexal cystic mass by ultrasonography at another hospital (128). All the women were white and ranged in age from 14 to 81 (mean 40) years.

To be eligible for randomisation the women had to have anechoic cystic masses of apparent serous content on ultrasonography with a diameter of between 40 and 70 mm, a well defined cystic wall, and not more than two thin septa (≤ 3 mm). Additional criteria were no free fluid in the pouch of Douglas, no history of malignant neoplasms, and no previous puncture of the cystic mass. Women with masses over 70 mm in diameter were considered ineligible as in our previous study we observed a negligible resolution rate after aspiration in cysts this large.

In the early months of the study women were examined with a full bladder by transabdominal ultrasonography with a 3.5 MHZ probe attached to a Toshiba SS90A (Toshiba Medical, Tokyo, Japan). In the last two years all women had transvaginal examination (after preliminary transabdominal evaluation of the whole pelvis) with a 6.5 MHZ probe attached to an Ansaldo AU450A (Ansaldo, Genoa, Italy).

After obtaining informed consent from the patients we randomly allocated women with eligible masses to simple observation (143) or puncture and aspiration of the mass (135). The treatment was decided by a randomisation table which was stored in a different part of the department and was unavailable to the doctors. We did not stratify by prognostic factors or use blocking.

The aim of the puncture was to aspirate the mass to dryness. Eighty one procedures were performed transabdominally and 54 were performed transvaginally. All procedures took place on an outpatient basis, without either anaesthesia or sedation, according to methods already described.¹⁸ We used chiba needles ranging in gauge from 18 to 21, and the aspirated fluid was fixed in 3.8% sodium citrate and sent for cytological examination in all cases.

At enrolment all the women had serum CA 125 concentrations measured. We did not refer women for

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treatment unless the concentration was over 100 U/l since we had previously observed a high incidence of false positive CA 125 results in patients with benign masses or tumour-like lesions.

All the women were asked to attend for follow up after six months. The cyst was considered to have resolved if no cystic lesion was detected or a follicle-like cyst not exceeding 20 mm in diameter was present. Patients were then referred to their gynaecologist for further treatment or follow up.

STATISTICAL ANALYSIS

Statistical evaluations were done with SAS software, release 6.08.¹⁹ We used standard statistical techniques

for the analysis of the distribution of the variables between the two groups, univariate analysis for the distribution between prognostic factors and outcome, and the χ^2 test and Mantel-Haenzel χ^2 for trend test respectively for dichotomous and ordered data. Continuous variables were grouped according to predefined cut offs, as shown in the tables. Multivariate analyses were done to fit a logistic model.²⁰ Two sided P values were calculated based on the χ^2 statistics.

The women lost to follow up were excluded from primary analysis and those having early surgery were included among treatment failures. We repeated the analysis including all subjects lost to follow up as treatment failures.

Table 1—Comparison of outcomes between women with benign cysts allocated to aspiration or observation according to the diameter of the cyst. Values are numbers (percentages) of women

Diameter (mm)	Outcome		
	Resolved	Persisted	Lost to follow up
Aspiration:			
≤45	24 (73)	9 (27)	3
46-50	12 (39)	18 (58)*	1
51-60	15 (39)	23 (61)	2
61-70	8 (29)	20 (71)	0
Observation:			
≤45	27 (56)	21 (44)	0
46-50	19 (47)	21 (53)	0
51-60	10 (37)	17 (63)	2
61-70	7 (27)	19 (73)	0

* Includes one patient who had surgery before end of six month follow up.

Table 2—Comparison of outcomes between the women with benign cysts randomised to aspiration or observation according to age. Values are numbers (percentages) of women

Age (years)	Outcome		
	Resolved	Persisted	Lost to follow up
Aspiration:			
≤30	15 (45)	18 (55)	2
31-40	17 (50)	17 (50)*	0
41-49	15 (47)	17 (53)	1
≥50	12 (40)	18 (60)	3
Observation:			
≤30	17 (47)	19 (53)	1
31-40	19 (54)	16 (46)	0
41-49	19 (43)	25 (57)	0
≥50	8 (31)	18 (69)	1

*Includes one patient who had surgery before end of six month follow up.

Results

In all, 245 women had cysts with no septum and 33 had cysts with one or two thin septa.

The median diameter of the cysts was 52 mm in the 143 women randomised to observation and 54 mm in those randomised to puncture and aspiration. The mean age in the groups was 40 (range 14-78) years and 41 (range 17-81) years.

Aspiration confirmed the presumption of serous content in 98% of cases. Three cysts had unexpected endometriotic content. The mean amount of aspirated fluid was 58 (range 15-170) ml. All patients had a serum concentration of CA 125 below 100 U/l at entry into the study and at follow up.

After six months we evaluated 269 subjects. Two women in the observation arm and six in the aspiration arm were lost to follow up and one woman had surgery before the end of follow up because of increased discomfort from the mass.

The cysts had resolved in 59 of 128 (46%) patients who had aspiration compared with 63 of 141 (45%) in the observation arm ($\chi^2 = 0.03$; $P = 0.862$). Table 1 shows that the rate of resolution was highly correlated with the diameter of the cyst; the likelihood of resolution fell significantly with increasing diameter (χ^2 for trend 17.24; $P < 0.0001$). The number of septa in the cysts had no significant effect on resolution (data not shown).

Table 2 shows the relation between resolution and age of the patients. Younger women (under 50) in both treatment arms seemed to have a higher rate of resolution, but the trend was not significant (χ^2 for trend 1.77; $P = 0.184$). Table 3 gives the results of the multivariate analysis including the diameter of the cyst, age of the subjects, and treatment. A similar analysis was also performed without grouping of the variables (data not shown). The results of the two analyses are consistent and show that the diameter of the cyst was the only significant predictor of the outcome. The same results were observed when the cases lost to follow up were considered as failures of the treatment (data not shown).

No severe complications, according to the classification described in a previous study,¹⁷ were observed with puncture aspiration. Five patients experienced mild transient pelvic discomfort and three had mild vagal reactions (sweating, dizziness) after the procedure. All these symptoms were self limiting and none of the women required admission to hospital or drugs. None of the women developed an infection after the procedure.

Of the 269 women followed up, 156 with persistent unchanged cysts were still being followed without surgery and without signs of malignant transformation 10 to 58 months after first diagnosis of the cyst. Seventy three women had surgery. In two cases cytological atypia had been detected at aspiration. In one case the final diagnosis at surgery was benign cystadenofibroma. Ultrasonography showed a unilocular cyst and the

Table 3—Multivariate analyses of factors predicting resolution. (Analysis with variables grouped)

	Proportion with resolution	Odds ratio (95% confidence interval)	χ^2 (df)	P value
Aspiration:				
No	63/141	1		
Yes	59/128	1.21 (0.73 to 2.02)	0.512 (1)	0.474
Diameter (mm):				
≤45	51/81	1		
46-50	31/69	0.48 (0.25 to 0.93)	17.926 (3)	0.0005
51-60	25/65	0.35 (0.18 to 0.70)		
≥61	15/54	0.23 (0.11 to 0.49)		
Age (years):				
≤30	32/69	1		
31-40	36/69	1.05 (0.52 to 2.11)	2.561 (3)	0.464
41-49	34/75	0.94 (0.48 to 1.86)		
≥50	20/56	0.60 (0.28 to 1.28)		

histopathological examination confirmed the simple nature of the cyst. The second patient had diagnosis of serous stage IA cystoadenocarcinoma of borderline malignancy. This subject had a cyst with one thin septum at transabdominal ultrasonography and did not have a transvaginal scan. Two thin papillae were detected at histopathological examination, but there was no sign of peritoneal seeding at the time of surgery and the patient has been followed for four years without signs of recurrence

Discussion

In the past two decades the increased use of new non-invasive diagnostic techniques such as ultrasonography has led to an increased rate of diagnosis of cystic masses, and an even higher rate may be expected in the future. Most cystic ovarian masses, particularly in teenagers and perimenopausal women, are functional. In a retrospective study performed in the early 1980s, functional cyst was the ultimate diagnosis in 66% of all ovarian "tumours" requiring laparotomy.²¹ Bhan observed that most persistent ovarian masses were tumour-like conditions.⁷

The diagnosis of an ovarian mass causes women anxiety, and they often pressurise doctors to remove it out of fear that they have ovarian cancer.⁸ However, unnecessary surgery represents a significant cost to the patient and to society. Surgery in young patients may interfere with fertility and increases the risk of ectopic pregnancies. Laparoscopy is becoming an alternative to laparotomy for benign adnexal masses,²² and this technique may reduce the hospital stay of patients, the sequelae, and complications leading to infertility in young patients. Nevertheless, operative laparoscopy is fairly expensive because of the wide use of disposable instruments. It is usually performed under general anaesthesia with its attendant risks and requires a short hospital stay. Any safe procedure further reducing costs, need for admission to hospital, and risks to the patient would be preferable to laparoscopy.

Several studies have confirmed that most simple ovarian cysts in postmenopausal women are benign,⁴ and sonographic criteria predicting benign cysts have been proposed. Granberg *et al* observed that the risk of a simple ovarian cyst diagnosed by ultrasonography being malignant was 0.3%.³ The only malignancy undiagnosed had an intracystic papilla and had been detected by transabdominal ultrasonography, which is less accurate than transvaginal examination. In prospective studies with transvaginal ultrasound no malignancy was ever observed in unilocular cysts.¹⁶

Our study shows that, in the short term, expectant management may spare women unwarranted intervention and that this policy may be successful even in perimenopausal women. The diameter of the cyst is the only independent significant parameter predicting the outcome. Puncture and aspiration did not increase the success rate of expectant management. It is possible that the rate of resolution with aspiration previously reported by us and others reflects the cases that would have resolved spontaneously.

CHARACTERISATION OF CYSTS

Transabdominal ultrasonography is probably inadequate for the accurate definition of cystic masses, particularly when expectant management is proposed. The woman with small foci of borderline tumours had small papillae at pathological examination, which had not been detected at transabdominal ultrasonography. After the introduction of transvaginal examination, none of the patients who had surgery had evidence of papillae at pathological examination and all had benign cysts.

In this study the cystic fluid was always sent for cytological assessment even though all cysts were

Key messages

- Ovarian cysts are much more common than previously thought in healthy and asymptomatic women
- Most of these masses are benign
- After follow up of six months the rate of resolution was similar in those who had had their cysts aspirated and those who had had them observed
- Only the diameter of the cyst was a significant independent prognostic factor for resolution
- A short expectant management is not risky for patients and allows resolution in more than a third of cases

considered benign according to ultrasonographic criteria. The predictive value of cytological examination is poor, and we used it only to minimise the risk of misinterpretation of malignancies. Seventy three of the 135 cysts that had been aspirated were eventually removed, and only one was found to be a stage IA cystoadenocarcinoma of borderline malignancy.

To reduce false negative test results, attempts at classifying adnexal tumours on the basis of their sonographic morphology must be kept simple.²³ Different scoring systems have been proposed for preoperative definition of ovarian masses. Technical improvements have allowed a small increase in the diagnostic accuracy since the first study by Meire *et al*,²⁴ but scoring systems simply aimed at identifying the nature of adnexal masses remain of limited clinical usefulness. Women with borderline findings will require surgery, irrespective of the score, because of the anxiety the uncertainty about the mass will create for both the women and their doctors.

According to the data of Campbell *et al*, a screening method with a sensitivity of 100% and allowing a reduction in the number of cysts operated on of 50% might avoid unnecessary surgery in 3% of women. New scoring systems with extreme sensitivity and positive predictive value might be of more clinical interest than other systems as they could reduce unnecessary surgery.

ASPIRATION OR OBSERVATION?

Our data do not support the superiority of aspiration over simple observation of simple cysts. Focusing on the content of a cyst may be misleading as the cystic wall, which produces the fluid, and not the content is responsible for the growth and persistence of the mass. However, it is unclear whether the women whose cysts resolve with no intervention are similar to those whose cysts resolve after aspiration. In cysts with a sonographically benign appearance, aspiration could be proposed as a second step before surgery if the cyst did not resolve after observation. Despite the lower resolution rate in older women, aspiration of symptomatic cysts might represent an alternative before surgery for subjects at high risk for general anaesthesia. However, because of the higher frequency of serous adenocarcinomas in this age category, aspiration should probably be limited to cysts without septa in women with low CA 125 concentrations.

Our results suggest that expectant management of apparently benign cysts is not hazardous even in postmenopausal women. Goldstein *et al*, reporting on 42 postmenopausal women with simple cysts, observed that all those who had surgery had benign lesions and 14 patients had been followed for up to 73 months without any change in size or character of the cyst.²⁵ Schwartz reported no malignancies developing in a series of over 30 patients with simple cysts whom he followed.⁸

In conclusion, an expectant management for three to six months does not seem to cause significant risks for the patients and may allow spontaneous resolution in about a third of cases. For the remaining patients with persistent unchanged masses, the possibility of prolonged expectant management deserves further investigation. Puncture aspiration of cysts does not provide better results than simple observation.

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Child spacing and two child policy in practice in rural Vietnam: cross sectional survey

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Abstract

Objective—To explore the reproductive pattern of women in rural Vietnam in relation to the existing family planning policies and laws.

Design—Cross sectional survey with questionnaires on reproductive history.

Setting—Tien Hai, a district in Red River Delta area, where the population density is one of the highest in Vietnam.

Subjects—1132 women who had at least one child under 5 years of age in April 1992.

Main outcome measures—Birth spacing and probability of having a third child.

Results—The mean age at first birth was 22.2 years. The average spacing between the first and the second child was 2.6 years. Mothers with a lower educational level, farmers, and women belonging to the Catholic religion had shorter spacing between the first and second child and also a higher probability of having a third child. In addition, women who had no sons or who had lost a previous child were more likely to have a third child.

Conclusion—Most families do not adhere to the official family planning policy, which was introduced in 1988, stipulating that each couple should have a maximum of two children with 3-5 years' spacing in between. More consideration should be given to family planning needs and perceptions of the population, supporting the woman to be in control of her fertility. This may imply improved contraceptive services and better consideration of sex issues and cultural differences as well as improved social support for elderly people.

Introduction

Population and family planning programmes have been implemented in Vietnam since the early 1960s.^{1 2} In 1988 a decree on population and family planning policies from the Council of Ministers stipulated a maximum of two children per couple with 3-5 years of spacing between them.³ The objectives of the 1993 policy clearly defined and reconfirmed the previous two child policy and the targets expressed already in 1980.⁴

The total fertility has declined from over six children per woman in the early 1970s to fewer than four in the late 1980s. The growth rate is still high, however, at 2.3% in 1992.⁵ Thai Binh province, in the Red River Delta area, has one of the highest population densities in the country and an actively implemented family planning programme.⁵⁻⁷

During the current transition period in Vietnam, introduced in 1986, many changes have taken place under the common label *doi moi* (renovation). Greater responsibility has been given to the individual and the family,⁸ and a positive impact of economic reforms has been demonstrated—for example, in rice production.⁹

We studied reproductive patterns and how the family planning policies have been followed during a period when the implementation of the policy was strong and the transition to a market economy was at an early stage.

Subjects and methods

This study was performed in Tien Hai district, one of eight districts of the Thai Binh province in the Red River Delta area in Northern Vietnam. Tien Hai (population 194 000) has 35 communes involved in rice growing, fishing, and salt production. The sample was selected by use of a multistage cluster sampling

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